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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/833,406

Applicant(s)

Boch

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 31, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21, 23-36, 39, and 41-45 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 23-36, 39, and 41-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

The request for the extension of time, filing under 1.114 and the preliminary amendment all dated 7-31-03 are acknowledged.

Claims included in the prosecution are 21, 23-29, 31-36, 39 and 41-45.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 21, 23-36, 39 and 41-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The negative limitations, ‘unsaturated phospholipid is not egg phosphatidylglycerol’ in claims 21 and 40, ‘do not comprise egg phospholipid’ in claim 30, ‘unsaturated phospholipid is not egg phosphatidylglycerol’ in claim 32, do not have support in the specification as originally filed and therefore, deemed to be new matter .**

Applicant’s arguments have been fully considered, but are not found to be persuasive. As already pointed out in the advisory action, the rejection is based on the ‘new matter’ and therefore, the arguments based on the case law do not appear to be applicable.

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 21, 23-25, 29, 32-33, 39 and 43-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Madden (5,389,378).

Madden discloses phospholipid formulations containing BPD-MA, DMPC (saturated lipid) and PC (unsaturated lipid). The phospholipids taught also include DMPG and negative phospholipids such as phosphatidic acid. The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film at 30 degrees (note the abstract, columns 5-8, Examples and claims). Although Madden does not explicitly disclose that the formulations contain micelles, the presence of micelles in the formulations is implicit as discussed below.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the claims have been amended to recite micellar formulations and Madden does not teach micellar formulations. This argument is not found to be persuasive since the method of preparation is the same in both prior art and in

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instant invention. It is noted from the specification on page 28, 1st paragraph where applicant states that “phospholipids used are those capable of forming liposomes, but also are able to result in the production of micelles if a high energy processing step is used for size reduction of multilamellar liposomes and the prior art uses high energy processing. The examiner cites in this context, the reference of Wan which discloses that phospholipids are amphiphilic in nature and have a propensity to form micelles and bilayers in an aqueous medium Col. 2, lines 3-5). Furthermore, instant claim language ‘comprising’ does not exclude liposomes which are also present in the prior art compositions. Applicant argues that Wan only discloses the ability of liposomes to encapsulate drugs and not micelles. This argument is not found to be persuasive since the reference of Young (cited of interest in this context) which is already of record teaches the usefulness of phospholipid micelles for the delivery of contrast agents.

5. Claims 21, 23-24, 27-29, 32-33, 35-36, 39 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu (5,707,608) or Desai (6,074,666) both are of record.

Liu discloses phospholipid formulations containing the claimed green porphyrins, DMPC and PG. The compositions include an antioxidant such as BHT and ascorbyl palmitate. The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film below 30 degrees (note the abstract, columns 6-12, Examples and claims).

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Similarly, Desai discloses phospholipid formulations containing the claimed green porphyrins, DMPC and DMPG. The compositions include an antioxidant such as BHT and ascorbyl palmitate. The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film below 30 degrees (note the abstract, columns 3-7, Examples and claims).

Although Liu, and Desai do not explicitly disclose that the formulations contain micelles, the presence of micelles in the formulations is implicit as discussed below.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the claims have been amended to recite micellar formulations and neither Liu nor Desai teach micellar formulations. This argument is not found to be persuasive since the method of preparation is the same in both prior art and in instant invention. It is noted from the specification on page 28, 1st paragraph where applicant states that "phospholipids used are those capable of forming liposomes, but also are able to result in the production of micelles if a high energy processing step is used for size reduction of multilamellar liposomes and the prior art uses high energy processing. The examiner once again points to the reference of Wan which discloses that phospholipids are amphiphilic in nature and have a propensity to form micelles and bilayers in an aqueous medium Col. 2, lines 3-5). Furthermore, as pointed out above, instant claim language 'comprising' does not exclude liposomes which are also present in the prior art compositions. Applicant argues that Wan only discloses the ability of liposomes to

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encapsulate drugs and not micelles. This argument is not found to be persuasive since the reference of Young (cited of interest in this context) which is already of record teaches the usefulness of phospholipid micelles for the delivery of contrast agents.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 21, 23-29, 31-36, 39 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden or Liu or Desai cited above in view of either Lentini (5,885,557) or Young (6,375,930) in further combination with Wan (5,329,029).

As discussed above,

Madden discloses phospholipid formulations containing BPD-MA, DMPC (saturated lipid) and PC (unsaturated lipid). The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film at 30 degrees (note the abstract, columns 5-8, Examples and claims).

Liu discloses phospholipid formulations containing the claimed green porphyrins, DMPC and PG. The compositions include an antioxidant. The method of preparation

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involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film below 30 degrees (note the abstract, columns 6-12, Examples and claims).

Similarly, Desai discloses phospholipid formulations containing the claimed green porphyrins, DMPC and PG. The compositions include an antioxidant. The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film below 30 degrees (note the abstract, columns 3-7, Examples and claims).

What is lacking in Madden, Liu, and Desai are the explicit teachings of micellar formulations containing phospholipids. Applicant on page 28 of the specification indicate that hydration to multilamellar vesicles followed by high energy processing step would result in the formation of micelles. Since the references teach the high energy processing steps, it would have been obvious to one of ordinary skill in the art that the compositions in the prior art would also contain micelles besides liposomes. It would appear that the references do not teach claimed porphyrin derivatives. Applicants in the specification indicate that the claimed derivatives are known in the art. The use of art known porphyrins in the liposomes of Madden or Liu or Desai, with the expectation of obtaining at least similar results, would have been obvious to one of ordinary skill in the art since these are photosensitizers with the same basic porphyrin structure.

Both Lentini, and Young discloses that photodynamic therapy could be practiced with photosensitizing material in carriers such as micelles and liposomes ((note the abstract, col. 7, line 62 through col. 8, line 29 of Lentini; abstract, col. 11, line 33

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through col. 13, line 43 of Young). Although Young discusses phospholipids, it is unclear whether he specifically advocates their use in the micelle formation.

Wan discloses that phospholipids are amphiphilic in nature and have a propensity to form micelles and bilayers in an aqueous medium Col. 2, lines 3-5).

The use of phospholipids as micellar forming structures in Lentini or Young for the delivery of benzoporphyrins of Madden or Liu or Desai would have been obvious to one of ordinary skill in the art since phospholipids are known active agent carriers and the reference of Wan shows that they have the ability to form either liposomes or micelles upon the addition of an aqueous medium.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments with regard to Madden, Desai and Wan have been addressed above. Applicant argues that Young is limited to the use of texaphyrins which are distinct from the hydro-monobenzo-porphyrin photosensitizers. This argument is not found to be persuasive since Young shows the ability of phospholipid micelles to encapsulate active agents and the primary references show the claimed porphyrins in phospholipid formulations.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

September 10, 2003